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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,151	10/30/2001	Jeffrey R. Balser	1242/49/2	8248

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/000,151	Applicant(s) BALSER ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-99* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a method of identifying a compound that modulates a biological activity of a potassium channel, classified in class 435, subclass 4.

II. Claims 20-33, drawn to a method of predicting a propensity of a candidate drug to induce a cardiac arrhythmia, classified in class 435, subclass 4.

III. Claims 34-47, drawn to a method of identifying a candidate compound that modulates the biological activity of a complex comprising a HERG channel polypeptide and a KCR1 polypeptide, classified in class 435, subclass 4.

IV. Claim 48, drawn to a modulator that modulates the biological activity of a complex comprising a HERG channel polypeptide and a KCR1 polypeptide, classification dependent upon structure of modulator.

V. Claims 49-50, drawn to a method for identifying a candidate compound as a modulator of KCR1 expression by measuring a detectable signal, classified in class 435, subclass 6.

VI. Claim 51, drawn to a modulator that causes in the detectable signal produced by the polypeptide and which transcriptionally modulates expression of KCR1, classification dependent upon structure of modulator.

VII. Claims 52-53, drawn to a method for identifying a candidate compound as a modulator of KCR1 expression by determining the amount of mRNA produced, classified in class 435, subclass 6.

VIII. Claim 54, drawn to a modulator that causes a measurable difference in the amount of mRNA transcribed, classification dependent upon structure of modulator.

IX. Claims 55-59, drawn to a method for modulating potassium channel function in a subject by administering an effective amount of a substance that provides expression of a KCR1-encoding nucleic acid molecule in a cell or tissue, classified in classification dependent upon structure of substance.

X. Claims 55-62, drawn to a method for modulating potassium channel function in a subject by administering an effective amount of a substance that provides expression of a KCR1-encoding nucleic acid molecule in a cell or tissue and

further comprising providing a gene therapy construct, classified in class 514, subclass 44.

XI. Claims 63-65, drawn to a method for modulating potassium channel function in a subject comprising administering a composition comprising a modulator of claim 36, classification dependent upon structure of modulator.

XII. Claims 66-78, drawn to a method of screening for susceptibility to a drug-induced cardiac arrhythmia in a subject, classified in class 435, subclass 6.

XIII. Claims 79-82, drawn to an oligonucleotide pair, wherein a first oligonucleotide of the pair hybridizes to a first portion of the KCR1 gene, classified in class 536, subclass 24.3.

XIV. Claims 83-84, drawn to a set of oligonucleotide primers comprising an anti-sense primer and a sense primer, classified in class 536, subclass 24.33.

XV. Claims 85-90, drawn to a kit for detecting a polymorphism comprising a reagent for detecting the presence of a I447V polymorphism of the KCR1 gene in a biological sample, classification dependent upon structure of reagent.

XVI. Claims 91-97, drawn to an assay kit for detecting the presence of a polymorphism of a KCR1 gene encoding a KCR1 polypeptide, the kit comprising a first antibody and a second antibody, classified in class 530, subclass 387.1.

XVII. Claims 98-99, drawn to an assay kit for detecting the presence of an antibody immunoreactive with a KCR1 polypeptide, the kit comprising human KCR1 polypeptide, classified in 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups IV, VI, VIII, and XIII-XVII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I-III, V, VII, IX-XII are different methods because they require different ingredients, process steps, and endpoints. Groups I-III, V, VII, and IX-XII are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of providing structure comprising a potassium channel polypeptide and a KCR1 polypeptide, contacting a test compound with the structure, determining biological activity of the potassium channel in the presence of the test compound, which is not required by the other inventions. Invention II requires search and consideration of providing structure comprising a potassium channel polypeptide and a KCR1 polypeptide, contacting a candidate drug with the structure, determining biological activity of the potassium channel in the presence of the test compound to predict the propensity of a candidate drug to induce a cardiac arrhythmia, which is not required by the other inventions. Invention III requires search and consideration of placing a cell comprising a HERG channel polypeptide and a KCR1 polypeptide in to a bathing solution, determining induced K+ current in the cell, adding a candidate drug to the bathing solution, determining induced K+ current in the cell, and comparing the induced K+ currents, which is not required by the other inventions. Invention V requires search and consideration of contacting a eukaryotic cell sample with a candidate compound, determining the amount of detectable signal to be produced by the polypeptide expressed by a reporter gene, and comparing the amount of produced signal detected in the presence and absence of candidate compound, which is not required by the other inventions. Invention VII requires search and consideration of contacting a eukaryotic cell sample with a candidate compound, determining the amount of mRNA transcribed, and comparing the amount of mRNA detected in the presence of absence of candidate compound, which is not required by the

other inventions. Invention IX requires search and consideration of efficacy of therapy of administration of a substance that provides expression of a KCR1-encoding nucleic acid molecule in a cell or tissue, which is not required by the other inventions. Invention X requires search and consideration of efficacy of therapy of administration of a gene therapy construct comprising a nucleotide sequence encoding a KCR1 polypeptide, which is not required by the other inventions. Invention XI requires search and consideration of efficacy of therapy of administration of a modulator to modulate potassium channel function, which is not required by the other inventions. Invention XII requires search and consideration of obtaining s biological sample from a subject and detecting a polymorphism of a KCR1 gene in the sample, which is not required by the other inventions.

c. Inventions IV and III, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as diagnostic assays.

d. Inventions VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as diagnostic assays or therapeutic assays.

e. Inventions VIII and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as diagnostic assays or therapeutic assays.

f. Inventions XIII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as therapeutic assays.

g. Inventions IV and I-II, V, VII, IX-X, and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups IV and I-II, V, VII, IX-X, and XII are unrelated product and methods, wherein each is not required, one for another. For example, the modulator of Invention IV cannot be used together with the claimed methods of Inventions I-II, V, VII, IX-X, and XII because these inventions do not recite the use or production of the modulator of Invention IV.

h. Inventions VI and I-III, VII, and IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups

VI and I-III, VII, and IX-XII are unrelated product and methods, wherein each is not required, one for another. For example, the modulator of Invention VI cannot be used together with the claimed methods of Inventions I-II, V, VII, and IX-XII because these inventions do not recite the use or production of the modulator of Invention VI.

i. Inventions VIII and I-III, V, IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups VIII and I-III, V, and IX-XII are unrelated product and methods, wherein each is not required, one for another. For example, the modulator of Invention VIII cannot be used together with the claimed methods of Inventions I-III, V, and IX-XII because these inventions do not recite the use or production of the modulator of Invention VIII.

j. Inventions XIII and I-III, V, VII, and IX-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups XIII and I-III, V, VII, and IX-XI are unrelated product and methods, wherein each is not required, one for another. For example, the oligonucleotide pair of Invention XIII cannot be used together with the claimed methods of Inventions I-III, V, VII, and IX-XI because these inventions do not recite the use or production of the oligonucleotide pair of Invention XIII.

k. Inventions XIV/XV/XVI/XVII and I-III, V, VII, and IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

different inventions of Groups XIV/XV/XVI/XVII and I-III, V, VII, and IX-XII are unrelated products and methods, wherein each is not required, one for another. For example, the products of Inventions XIV/XV/XVI/XVII cannot be used together with the claimed methods of Inventions I-III, V, VII, and IX-XII because these inventions do not recite the use or production of the products of Inventions XIV/XV/XVI/XVII.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate search requirement, different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of identifying a compound that modulates a biological activity of a potassium channel by providing a structure comprising a potassium channel polypeptide and a KCR1 polypeptide, wherein the structure comprises:

a. a cell
b. a lipid bilayer
c. a cell that has been transfected with a nucleic acid encoding an exogenous KCR1 polypeptide
d. a cell that has been transfected with a nucleic acid encoding an exogenous potassium channel polypeptide

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Applicant selects Invention I or II, one species from the structure group must be chosen to be fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
June 30, 2003

Gary L Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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